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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/608,892 06/30/00 HAALAND

F P-4948

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EXAMINER

BHATTI, T

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

10/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File
copy
Office Action Summary

Application No.

09/608,892

Applicant(s)

HAALAND ET AL

Examiner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Status of the Claims

Claims 1-30 are currently pending.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4 and 12-18, drawn to peptides and culture comprising peptides, classified in class 530, subclass 300+.
 - II. Claims 5-11, 19 and 30, drawn to peptide libraries, classified in class 436, subclass 536.
 - III. Claims 20-25, drawn to methods of enhancing/inhibiting protein production, classified in class 435, subclass 842.
 - IV. Claims 26-~~29~~³⁰, drawn to recombinant methods of making peptides, classified in class 435, subclass 69.1.
2. The inventions are distinct, each from the other because of the following reasons:
3. The individual peptides of Group I are independent and/or distinct from the library of peptides of Group II since the library encompasses compositions which are subcombination and combination of peptides which are potentially independent and/or distinct from the individual peptide species. Additionally, the claiming of libraries as compared to individual peptide species encompasses issues (e.g. under 35 USC 112, 102 and 103) which are different. Further, the compound as compared to the library which incorporates combinatorial principles not presented

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by a single peptide Markush claim necessitates a diverse and different, separately burdensome manual and computer sequence and bibliographic searches of the patent and non-patent literature. Additionally, the classification search for Group I and II are different and separately burdensome.

4. Inventions (I or II) and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as utilizing a transcription regulating protein or antisense protocol; and the product as claimed can be used in a materially different process of using that product as in an intermediate(s) for producing a protein or for protein affinity purification.

5. Inventions (I or II) and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different product such as the use of recombinant methods to make fusion proteins in which the protein has an amino acid sequence different from the peptides; and that the product as claimed can be made by another and materially different process such as solid or liquid phase peptide syntheses..

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6. The method invention of Group III is independent and/or distinct from the method invention of Group IV since the different methods have different objectives, utilize different method steps and reaction conditions and required different and separately burdensome manual and/or computer patent and literature searches.

7. Because these inventions are distinct for the reasons given above and:

- a. have acquired a separate status in the art as shown by their different classification;
- b. require different and independently burdensome manual/computer patent and non-patent literature searches; and/or
- c. because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Restriction/Election of Species (FOR GROUPS I-IV ABOVE)

The above Groups I-IV encompass tri-, tetra-, penta-, hexa- peptide markushes (e.g. see claims 1 or 30) or peptide libraries (e.g. claim 5) or the use or making thereof which lack any fixed peptidic structure or common core necessary to elicit a common activity (e.g. improper Markush group) and/or additionally would encompass a potentially large number of diverse peptide compounds of different sequence (e.g. length and composition) which possess different physicochemical properties, which are capable of separate manufacture and/or use and which require separate and/or divergent manual/computer structure, bibliographic patent and non-patent literature searches which are separately and individually burdensome.

Accordingly, applicant is FIRST required under 35 U.S.C. 121 to elect:

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- I. A single class peptide length (e.g. tri- OR tetra- OR penta- OR , hexa- peptide
AND
- ii. A single peptide species (e.g. a single sequence id no.) within the scope of the elected
peptide length in I. above.

for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is required under 35 U.S.C. 121 to elect a class of peptide length and a single peptide species on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable

8. **Applicant is advised that a reply to all of the above requirements must include an identification of the species that is elected consonant with these requirements, and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Due to the complexity of the above Restriction/Election telephone practice was not attempted.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Bhatti whose telephone number is (703) 605-1203

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat (art unit 1627), can be reached at (703)308-0570.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Tahira Bhatti (art unit 1627)

September 27, 2001

BENNETT CELSA
PRIMARY EXAMINER

